



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Web-based Resource for Youth about Clinical Research (NHLBI)

SUMMARY: In compliance with the requirement of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Victoria Pemberton, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr., Room 8102, MSC 7940, Bethesda, MD 20892-7940, or call non-toll-free number 301-435-0510, or E-mail your request, including your address to pembertonv@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Web-based Resource for Youth about Clinical Research (NHLBI), 0925-New, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to develop a comprehensive web-based resource for youth with chronic illnesses or diseases that will attempt to increase knowledge, self-efficacy, and positive attitudes towards participation in various clinical trials and research. As a result of the proposed web-based resource, the knowledge gained from developing and testing this web-based resource will ultimately help equip youth to make informed

decisions about clinical research and increase motivation to participate in that research. In addition, the knowledge gained will be invaluable to the field of clinical research given the need for more clinical trials with youth. Specifically, the proposed web-based resource will be an interactive, multimedia, developmentally appropriate resource for youth to be educated about pediatric clinical trials. The resource will be developed for youth aged 8 to 14 years. The theme of “investigative cyber-reporting” will be used throughout and will include youth making a series of decisions about different aspects of participating in clinical research studies. Youth will be tasked with the responsibility of learning all they can about clinical research trials in order to facilitate their knowledge and decision-making processes. Language typically used in journalism and design elements reminiscent of journalism will be incorporated into the content, design, and layout of the resource. There are three main components that will comprise the web-based resource. These include an interactive learning module, full length video testimonials, and an electronic comic book. The benefits and necessities for this particular research on pediatric clinical trials are congruent with NHLBI’s research goals and mission statement: attempting to assist in the enhancement of the health of individuals so that they can live longer and more fulfilling lives. The current lack of knowledge surrounding pediatric clinical trials can be dangerous and unhealthy towards the lives of youth, becoming a large public health need.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 164.

Estimates of Hour Burden

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Individual Interview Questionnaire	Individual Interviews Study	9	1	2	18
One-to-One Evaluation Questionnaire	One-to-One Evaluation Study	5	1	2	10
Pre-Post Study Questionnaire	Pre-Post Feedback Study	34	1	4	136

Dated: February 23, 2015.

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[FR Doc. 2015-05592 Filed: 3/11/2015 08:45 am; Publication Date: 3/12/2015]